



**IN THE
UNITED STATES
PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Dzeng et al.

CASE: Stanford S03-060

SERIAL NO.: 10/803,235

**DECLARATION UNDER
37 C.F.R. § 1.132**

FILED ON: 27 March 2004

FOR: A Transesophageal Heat
Exchange Catheter for
Cooling of the Heart

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

EXAMINER: Gibson, Roy D.

ART UNIT: 3739

DECLARATION UNDER 37 C.F.R. § 1.132

Sir,

I, **Elizabeth Dzeng**, declare as follows:

1. I am one of the named inventors on the above-referenced application for patent.
2. I am a physician in residence at the Columbia New York Presbyterian Hospital in New York, NY. I earned my medical degree and MPH at Johns Hopkins and her BS and MS at Stanford University. I also hold an M.Phil. in Development Studies from the University of Cambridge, United Kingdom, where I was a Gates Scholar. As a graduate student in Chemical Engineering at Stanford, I participated in the Biodesign Innovation Program where I focused on the invention of devices to preserve cardiac function during a myocardial infarction. During this time, I had the opportunity to gain expertise in the field of non-invasive cooling and the

process of biodesign invention from conception to its end product. I am familiar with the human anatomy, particularly in regards to the structures of passageways, such as the esophagus and the gut, the bronchi and the lungs, major blood vessels, lymph vessels, and canals and sinuses, such as those found in the brain, kidneys, and reproductive system.

3. I have read the Examiner's Office action, mailed January 14, 2009. The Examiner has rejected claims 13, 14, and 34-50 under 35 U.S.C. § 103(a) as being unpatentable over Stull (US Patent No. 7,077,825) in view of Joye et al. (US Patent No. 5,972,979). The Examiner stated that Stull discloses the catheter, transducer, marker, and balloon structure of claim 13 except for the longitudinal disposed groove on the outer surface of the balloon and a guidewire lumen. The Examiner then stated that Joye discloses a cooling balloon catheter with a guidewire and guidewire lumen (Office action at page 2, last paragraph). Although neither of the cited references disclose a longitudinal disposed groove on the outer surface of the balloon, the Examiner stated that "a typical heat exchange catheter balloon (flexible and pliable) can be *partially inflated* as required to form a groove *as the balloon conforms to the shape and size of a similarly shaped anatomical structure*" (Office action at page 3, second paragraph; my emphasis).
4. I know of no anatomical structure into which the heat exchange catheter system of the invention would be placed that could in any way cause a groove to form in the balloon as suggested by the Examiner. Further, as noted in the instant application, we stated that one alternative embodiment of the invention was a balloon, when inflated, having a groove disposed longitudinally on its outer surface, the groove being present to allow swallowing (e.g., specification at page 19, paragraph 80, last three lines and continued on page 20, lines 1-2). I would suggest that, if the partially inflated balloon could conform to the shape and size of an anatomical structure thereby forming a groove, the object of having the groove (to allow swallowing or the like) would be defeated. Blocking the lumen of the anatomical

structure in this way could prevent passage of air, fluids, etc., that otherwise may compromise the comfort and safety of a patient. In my opinion, this may cause a patient discomfort and is therefore not desired.

5. I would contend that the balloon device of Stull, even when partially inflated, could not form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure (presumably an anatomical structure having a ridge disposed upon the interior surface of the structure), as stated by the Examiner, as there are no similarly shaped anatomical structures to my knowledge.
6. The Stull reference therefore is not a prior art anticipating reference as defined by 35 U.S.C. § 102.
7. The Stull reference therefore is not prior art as defined by 35 U.S.C. § 103(a).
8. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Elizabeth Dzeng, M.D., MPH, M.S., M.Phil.

Dated: June 9, 2009